IMPROVED BULKING AGENT COMPOSITION

The present invention relates to medicinal compositions comprising fibre or saccharide bulking agents.

Ingestible fibre- or saccharide-containing compositions for the relief of gastric and digestive dysfunctions are known. Examples of such compositions include granular psyllium husk fibre (ispaghula) intended to be stirred in measured amounts into a volume of liquid, usually water or soft drinks. After stirring, the drinking composition is intended to be quickly imbibed due to the propensity of the ispaghula to absorb water readily and swell to form a viscous gel-like mass. It is the property of water absorption which has the desired characteristic of fibre or saccharide-containing ingestible compositions for gastric and digestive dysfunctions. Once the fibre or saccharide-containing composition has absorbed water to produce the gel-like mass, the mass is relatively insoluble and fibrous, and is transported through the gut quickly with minimal digestion, helping to alleviate constipation and other digestive dysfunctions.

Other forms, such as capsules forms for ingestion, are also available, such capsules being designed to be broken down in the gut, wherein the released fibre or saccharide bulking agent absorbs water from the gut to form the viscous mass.

However, for beneficial ease-of-use properties, a particulate form is particularly advantageous to the end user, as this can be stirred into a volume of liquid, for a more pleasant taste, and the granular form of the fibre

or saccharide absorbs water from the gut more quickly than a capsule form. However, there are a number of problems involved in using a granular form of the fibre- or saccharide-containing ingestible compositions.

Primarily, it is desirable for the ingestible compositions to disperse easily in liquid, for the user's convenience and/or so that the resultant drink is more palatable and/or easier to swallow. Any new composition must be as good as or, preferably, better than, existing compositions in this respect.

Secondly, the handling of some ingestible fibre- or saccharide-containing compositions is not straightforward. For example in commercial production ispaghula is milled then isopropyl alcohol and a granulating agent polyvinyl pyrollidone are added. These steps aid handling of the compositions during manufacturing, before the isopropyl alcohol is removed prior to packaging the product for sale. The granulation also aids the dispersion of the ispaghula into a volume of liquid, prior to ingestion. However, the use of the granulating agent and isopropyl alcohol increases the cost of production and the use of the isopropyl alcohol is undesirable from an environmental and a health and safety perspective.

Thus, from the foregoing, it is apparent that there is a need for the provision of an ingestible composition which comprises a fibre or saccharide bulking agent, in which the ingestible composition disperses easily in an aqueous liquid and/or is of improved manufacture.

It has now been determined that an ingestible composition comprising a fibre or saccharide bulking agent, which also includes an ingestible silica in conjunction with an ingestible surfactant, can offer benefit in the manufacture of the ingestible composition, and can increase the rate at which the ingestible composition disperses in water or other ingestible liquid.

Therefore, according to the present invention there is provided an ingestible composition comprising a fibre or saccharide bulking agent, an ingestible silica and an ingestible surfactant wherein said composition is in a form so that in use it is dispersed in a liquid prior to ingestion.

According to a second aspect of the invention there is provided an ingestible composition comprising a fibre bulking agent selected from ispaghula or a bran, an ingestible silica, and an ingestible surfactant.

The presence of both an ingestible silica and an ingestible surfactant can confer significant, eg synergistic, benefits. For example when the fibre or saccharide bulking agent is ispaghula the ternary composition has outstanding wettability properties, and is easy to manufacture, for example by simple blending.

Suitably the fibre or saccharide bulking agent is a natural ingestible fibre (by which term we include herein fibre extracts). Plant-derived fibre bulking agents are preferred, such as cellulose or derivatives thereof; psyllium husk fibre (ispaghula); or brans such as corn, oat, wheat or rice brans. Animal-derived fibre, fruit-

derived fibre and/or synthetic ingestible fibres may also be used. Examples include barley fibre, pea fibre, sugar beet fibre and β-glucan.

Particularly preferred as a fibre bulking agent is ispaghula.

The ispaghula may comprise whole ispaghula seeds, but preferably at least part of the ispaghula comprises separated ispaghula seed husks. More preferably the ispaghula comprises at least 50% wt separated ispaghula husks, most preferably at least 95% wt separated ispaghula husks. Suitably the remainder of the ispaghula comprises other seed parts and/or other ispaghula plant materials. In preferred compositions the seed kernels themselves have been substantially removed to leave the husks.

If the bulking agent is a saccharide-containing bulking agent it is suitably a polysaccharide, an arabinoxylan, a galactomannan, a glucomannan, preferably an algin, especially alginic acid or a salt derivative thereof, such as calcium alginate, magnesium alginate, sodium alginate or potassium alginate.

Algins may be found in and isolated from various organisms, in particular from algae belonging to the order *Phaeophyceae* and soil bacteria such as *Azotobacter vinelandii* and *Azotobacter crococcum* and from several strains of *Pseudomonas* bacteria. Common algal sources of algins include *Laminaria digitata, Ecklonia maxima, Macrocystis pyrifera, Lessonia nigrescens, Ascophyllum nodosum, Laminaria japonica, Durvillea antartica, Durvillea potatorum* and, especially, *Laminaria hyperborea*.

Alginic acid is a linear hetero-polysaccharide comprising units of ß-D-mannuronic acid and α-L-guluronic acid. Alginic acid may comprise homopolymeric sequences of mannuronic acid, homopolymeric sequences of guluronic acid, and mixed sequences of mannuronic acid and guluronic acid units.

Salts of alginic acid used may include alkali metal salts, for example sodium and potassium salts, and ammonium and alkanolamine salts. Alkali metal salts are of particular interest.

The term "algins" as used herein includes alginic acid and salts of alginic acid, irrespective of the relative proportion of mannuronic and guluronic units, and is intended to include glycolated or alkoxylated derivatives, especially those derivatised with propylene glycol. However, preferred compounds are not alkoxylated or glycolated.

Suitably the fibre or saccharide bulking agent is present in the ingestible composition in an amount of at least 10wt%, preferably at least 30wt%, and most preferably at least 40wt% of the total weight of the ingestible composition.

Suitably the fibre or saccharide bulking agent is present in the ingestible composition in an amount up to 90wt%, preferably up to 80wt%, and most preferably up to 75wt% of the total weight of the ingestible composition.

Suitably the silica is fumed or precipitated synthetic or natural silica. The silica may be amorphous or crystalline.

Suitably the mean particle size of the silica is at least 5nm, preferably at least 10nm.

Suitably the mean particle size of the silica is up to 5μm, preferably up to 0.75μm, more preferably up to 0.5μm, and most preferably up to 0.2μm.

The silica material that is used may typically contain 0.1 to 2.5wt% alumina (Al_2O_3), preferably 0.5 to 2wt% alumina, and most preferably about 1wt% alumina, based on the weight of the silica.

One suitable silica material is Syloid 244 which is amorphous silica, has a mean particle size of about 3μm and is provided by W R Grace & Co. Another suitable silica materials is Silox 15,also from W R Grace & Co., and which has a mean particle size of about 4μm.

Another suitable silica material is Huber Zep 49 which is amorphous silica from J M Huber Corporation and contains about 1 wt% alumina.

Another suitable silica is Aerosil 200 from Degussa Company. It contains less than 0.05 wt% alumina and has a mean particle size of 12 nm.

Preferably the silica is colloidal silica, and a preferred silica is a colloidal silica which is sold under the trade mark CAB-O-SIL, by Cabot Inc, USA.

Suitably the specific surface area of the silica is at least $50m^2\ g^{-1}$, preferably at least $150m^2\ g^{-1}$.

Suitably the specific surface area of the silica is up to $400m^2\ g^{-1}$, preferably up to $300m^2\ g^{-1}$ most preferably up to $200m^2\ g^{-1}$.

Suitably the silica is present in the ingestible composition in an amount at least 0.01wt%, preferably at least 0.05wt%, more preferably at least 0.1wt% and most preferably at least 0.25wt%, of the total weight of the ingestible composition.

The upper limit of silica in the ingestible composition may be up to 11 wt%. Suitably the silica may be present in the ingestible composition in an amount up to 5wt%, preferably up to 2wt%, more preferably up to 1wt%, and most preferably up to 0.6wt%, of the total weight of the ingestible composition.

Preferably the ingestible surfactant is a polyethylene-, polypropylene-, or polyoxyethylene-based surfactant. Suitable polyethylene or polyoxyethylene-based surfactants include polyethylene glycols and polyoxyethylene sorbitan fatty acid esters (polysorbates).

Suitable polyethylene glycols have a molecular weight of between 200 and 40,000, preferably between 200 and 1,000, and more preferably between 200 and 600. Suitable

Example 5

The wettability testing was repeated for a composition containing barley fibre as the bulking agent, Tween 80 and CAB-O-SIL. The samples were tested immediately on preparation. The results of the experiment are shown in Table 9.

Table 9 - Wetting times of Barley Fibre and Tween 80 / CAB-O-SIL Mixtures.

Barley Fibre (g)	Tween 80 (mg)	Cabosil (mg)	Wetting Time (seconds)
3.5	0	0	>600
3.5	0	200	280
3.5	0	400	200
3.5	30	0	129
3.5	30	200	102
3.5	30	400	81
3.5	60	0	77
3.5	60	200	56
3.5	60	400	55
3.5	100	0	30
3.5	100	200	24
3.5	100	400	22

The results show that for a given amount of Tween, addition of CAB-O-SIL to the composition significantly improves wettability of barley fibre.

Example 6

The wettability testing was repeated for a composition containing green pea fibre as the bulking agent, Tween 80 and CAB-O-SIL. The samples were tested immediately on preparation. The results of the experiment are shown in Table 10.

Table 10 - Wetting times of Green Pea Fibre and Tween 80 / CABO-O-SIL Mixtures.

Green Pea Fibre (g)	Tween 80 (mg)	Cabosil (mg)	Wetting Time (seconds)
14.2	30	0	42
14.2	60	0	18
14	30	50	12
14	30	100	8
14	0	50	30
14	0	100	13

The results show that for a given amount of Tween, addition of CAB-O-SIL to the composition significantly improves the wettability of pea fibre.

Example 7

The wettability of sodium alginate as the bulking agent was tested. 0.5g of each sample was sprinkled over water and the time taken to wet was recorded.

Sodium Alginate (g)	Tween (g)	Colloidal silica (g)	Wetting Time (seconds)
1	-	-	25
0.97	-	0.03	20
0.952	0.04	0.008	15

(Table 11 shows the amounts of each component in a 1g sample. 0.5g of sample was used for each test).

The results show that the addition of Tween and colloidal silica significantly reduces wetting time. The reduction in wetting time is not only seen when compared with a sample of untreated sodium alginate but is also seen when compared with a sample containing sodium alginate and colloidal silica. When Tween is added, significantly less colloidal silica is required to result in a significant reduction in the wetting time of the alginate.

Claims

1. An ingestible composition comprising a fibre or saccharide bulking agent, an ingestible silica, and an ingestible surfactant wherein said composition is in a form so that in use it is dispersed in a liquid prior to ingestion.

2. An ingestible composition according to claim 1 wherein said composition in particulate or granular form.

3. An ingestible composition as claimed in claim 1 or 2 wherein the fibre bulking agent is ispaghula.

4. An ingestible composition as claimed in claim 1 or 2 wherein the bulking agent is a polysaccharide-containing bulking agent comprising an algin.

5. An ingestible composition according to claim 1 or 2 wherein the fibre bulking agent is cellulose or a derivative thereof.

6. An ingestible composition comprising a fibre bulking agent selected from ispaghula or a bran, an ingestible silica, and an ingestible surfactant.

7. An ingestible composition according to claim 6 wherein the fibre bulking agent is ispaghula.

8. An ingestible composition as claimed in any preceding claim wherein the particle size of the silica is between 5nm and 5μm.

9. An ingestible composition as claimed in any preceding claim wherein the specific surface area of the silica is between 50 and 400gm^{-2}.

10. An ingestible composition as claimed in any preceding claim wherein the silica is present in an amount of between 0.01wt% and 5wt% of the total weight of the ingestible composition.

11. An ingestible composition as claimed in any preceding claim, wherein the ingestible surfactant is a polyethylene-, polypropylene-, or polyoxyethylene-based surfactant.

12. An ingestible composition as claimed in claim 11 wherein the polyethylene-based surfactant is a polyethylene glycol.

13. An ingestible composition as claimed in claim 12 wherein the polyethylene glycol has a molecular weight of between 200 and 40,000, preferably between 200 and 1,000.

14. An ingestible composition as claimed in claim 11 wherein the polyoxyethylene-based surfactant is a polyoxyethylene sorbitan fatty acid ester.

15. An ingestible composition as claimed in claim 11, wherein the surfactant is a polyoxyethylene monostearate or a glycerol polyethylene glycol oxystearate.

16. An ingestible composition as claimed in any preceding claim wherein the ingestible surfactant is present in an

amount of between 0.01wt% and 5wt% of the total weight of the ingestible composition.

17. An ingestible composition as claimed in claim 16 wherein the ingestible surfactant is polyethylene glycol and is present in an amount of between 0.1wt% and 2wt% of the total weight of the ingestible composition.

18. An ingestible composition as claimed in claim 16 wherein the surfactant is a polyoxyethylene sorbitan fatty acid ester and is present in an amount of between 1wt% and 2wt% of the total weight of the ingestible composition.19.

19. A method of making an ingestible composition comprising a fibre or saccharide bulking agent, an ingestible silica, and an ingestible surfactant, the method comprising the step of blending the fibre or saccharide bulking agent with the ingestible silica and the ingestible surfactant; preferably without the employment of isopropyl alcohol or more preferably of any solvent; and preferably without the employment of polyvinyl pyrollidone or more preferably of any granulating agent.

20. An ingestible composition or its manufacture substantially as described herein.